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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/354,450	12/12/1994	GARY K. MICHELSON	P10936V	3041

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EXAMINER	
DEMILLE, DANTON D	

ART UNIT	PAPER NUMBER
3764	25

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary	Application No.	Applicant(s)	
	08/354,450	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Danton DeMille	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In view of the previous examiner's remarks in the final rejection stating the specification does support the limitation that the distance from the top of the projection to the central axis of the shaft is greater than the radius of the head and that applicant amended the claims accordingly and that this examiner doesn't believe that there is proper support for such a limitation, the following is a new office action.

Specification

The amendment filed 7/23/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "each of said flexible projections having a height measured from a surface of said shaft, the sum of the height of one of said flexible projections and the radius of said shaft being greater than the radius of said flexible member".

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention.

There appears to be no support in the specification for the above noted language or the criticality why this dimension is now claimed. Applicant points to page 8 and lines 3-16 for support of the projections having a greater radius than the flexible member however, this

language never states that the projections extend greater than the flexible member. Nor does it state why and what advantage this has over the prior art. If this dimension is so critical then why doesn't the specification clearly set this distinction out? Lines 3-10 describe an embodiment that has a 2.0 mm diameter shaft and lines 11-16 describe an embodiment that has a 1.25 mm diameter shaft. Appellant takes the radius of the shaft of the smaller embodiment and subtracts it from the radius of the flexible member of the larger embodiment. This gives a misleading dimension of the height of the flexible member. At the beginning of the third line from the bottom of page 7 of the brief appellant states that the diameter of the shaft is taken from page 8, line 12 of the specification and at the beginning of the second line from the bottom of page 7 of the brief appellant states that the diameter of the flexible member is taken from page 8, line 6 of the specification. In the specification page 8 one can clearly see that line 12 is under line 11 that states "In the alternative embodiment of the present invention...." which is a smaller embodiment from the lines above line 11 which is where appellant got the dimension for the flexible member in line 6 and is the larger sized embodiment. Appellant takes the radius of the smaller rivet being 0.625 mm, half of the smaller diameter 1.25 mm, and subtracts that from the outer radius of the flexible member 118 of the larger rivet being 1.25 mm, half of the larger diameter dimension 2.5 mm. This yields a number that is not a true dimension in any embodiment. Moreover, appellant takes this false dimension 0.625 mm, which is supposed to be the height of the flexible member above the outside surface of the shaft, and compares it to the raw radius of the projections which appellant states has to be greater than 1 mm because the overall diameter of the rivet is 2 mm. The second number includes the diameter of the shaft whereas the first number subtracts the diameter of the shaft. None of these arguments make any sense.

Applicant also attempts to support this claim language by alleging that figure 5 shows the sum of the height of one of the flexible projections and the radius of the shaft being greater than the radius of the flexible member however, this is not true. No such relationship can be gleaned from the figure. There is no showing whatsoever in figure 5 that the projection extends a greater distance than the flexible member. Applicant is relying on information that is not there.

There also appears to be no support in the specification for the limitations recited in claim 24. Claim 24 recites that "no more than two said apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft at any point along said shaft". Where in the specification is support for this? The drawings clearly don't show this embodiment. It would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis. There is also no support in the specification for this critical feature. It is not clear how appellant can claim that no more than two projections lie in a perpendicular plane when it appears all four projections lie in the same perpendicular plane.

Claims 19-24, 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not adequately described as set forth in the above objection to the specification.

Claim Rejections - 35 USC § 103

Claims 19, 22 and 26-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren. Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of projections extending from said shaft and the flexible member at the other end. He also discloses that the rivet is made of

biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion. Due to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that rivet of Warren would comprehend the claimed resilient characteristic at least to some extent. It is not clear exactly how the claimed rivet is different from Warren's rivet however, it would have been obvious to modify the rivet of Warren as desired so that its head was flexible enough to conform to the angle of the tissue. This modification would have been obvious for one of ordinary skill to have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation.

Warren teaches "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." column 6, lines 46-49. Warren goes further to state, "for other purposes (e.g., for attaching ligaments to bones in the leg region), other dimensions may be more desirable." Clearly the dimensions and relative sizes can be modified dependent on practical intended use considerations. Warren teaches that the fastener can be thinner. If the device is intended to be used in softer tissue then the thickness of the fastener can be reduced. A thinner fastener would make a more flexible fastener. Softer tissue would require the projections to be a little longer to more securely engage the softer tissue. Such considerations are obvious to one of ordinary skill in the art and not a patentable distinction. Warren teaches all of the same structure claimed the only difference is relative dimensions.

Even if the specification some how supported that fact that the projections extend further than the flexible member such relative dimensions do not involve an inventive step. Such differences don't appear to have any particular advantage over the prior art. In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Warren has all of the same structural elements claimed. The only difference is relative sizes of the threads to the head and the thickness of the head. Such dimensions are not viewed as being critical or overcome a problem in the prior art and therefore are not patentable.

Claims 20 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Bays et al. Warren discloses the rivet as discussed above. He does not disclose the driver as claimed.

Bays teaches the driver as discussed in the previous office action. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren with the driver as taught by Bays to complete the operation of installing the rivet in use. This would have been obvious for Bays teaches that his driving means allows the user to apply the force necessary to correctly place the rivet within the tissue. Appellant is to note that the lengths of his driver's elements are well within the realm of the artisan of ordinary skill and is not inventive to discover the optimum or workable ranges by routine experimentation.

Claims 23 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Duncan. Warren may not teach the staggered projections as claimed however Duncan teaches rivets that have radially staggered projections. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren to stagger the projections as taught by Duncan so the rivet will be better secured within the body.

ddd
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